

EB 136719595 US

10-02-07

15-1614

PTO/SB/21 (10-07)

Approved for use through 10/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL  
FORM**

OCT 01 2007

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

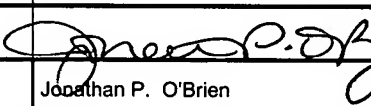
Application Number	10/526,839
Filing Date	11/01/2005
First Named Inventor	Boriack-Sjodin, Paula Ann
Art Unit	1614
Examiner Name	Timothy P. Thomas
Attorney Docket Number	124269/A165 US/00075

**ENCLOSURES (Check all that apply)**

- |  |  |  |
|--|--|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input checked="" type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Reply to Missing Parts/<br>Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts<br>under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a<br>Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br>Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><br><input type="checkbox"/> Appeal Communication to Board<br>of Appeals and Interferences<br><br><input type="checkbox"/> Appeal Communication to TC<br>(Appeal Notice, Brief, Reply Brief)<br><br><input type="checkbox"/> Proprietary Information<br><br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify<br>below):<br>Repy to US Restriction Requirement |
|--|--|--|

Remarks

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	Miller, Canfield, Paddock and Stone
Signature	
Printed name	Jonathan P. O'Brien
Date	October 1, 2007

Reg. No. 50,852

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature

Typed or printed name

Date

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

#555520

EB 136719595 US

PTO/SB/17 (10-07)

Approved for use through 06/30/2010. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL**  
**For FY 2008**

OCT 01 2007

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 120.00

**Complete if Known**

Application Number	10/526,839
Filing Date	11/01/2005
First Named Inventor	Boriack-Sjodin, Paula Ann
Examiner Name	Timothy P. Thomas
Art Unit	1614
Attorney Docket No.	124269/A165 US/00075

**METHOD OF PAYMENT (check all that apply)**
☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account Deposit Account Number: 503654 Deposit Account Name: Miller Canfield Paddock and Stone

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee  
☐ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	210	105
Multiple dependent claims	370	185

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 20 or HP = _____ x _____ = _____			
HP = highest number of total claims paid for, if greater than 20.			
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 3 or HP = _____ x _____ = _____			
HP = highest number of independent claims paid for, if greater than 3.			

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$260 (\$130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____				

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Response to US Restriction

120.00

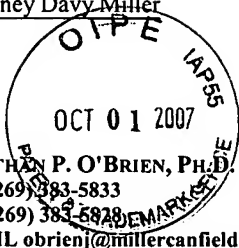
**SUBMITTED BY**

Signature 	Registration No. (Attorney/Agent) 50,852	Telephone 269-383-5833
Name (Print/Type) Jonathan P. O'Brien		Date October 1, 2007

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Founded in 1852  
by Sidney Davy Miller



JONATHAN P. O'BRIEN, PH.D.  
TEL (269) 383-5833  
FAX (269) 383-5828  
E-MAIL obrienj@millercanfield.com

# MILLER CANFIELD

Miller, Canfield, Paddock and Stone, P.L.C.  
444 West Michigan Avenue  
Kalamazoo, Michigan 49007  
TEL (269) 381-7030  
FAX (269) 383-5828  
[www.millercanfield.com](http://www.millercanfield.com)

MICHIGAN: Ann Arbor  
Detroit • Grand Rapids  
Kalamazoo • Lansing  
Saginaw • Troy  
FLORIDA: Naples • Pensacola  
ILLINOIS: Chicago  
MASSACHUSETTS: Cambridge  
NEW YORK: New York  
CANADA: Windsor, ON  
POLAND: Gdynia  
Warsaw • Wroclaw

October 1, 2007

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Re: Inventors: Wen-Cherng Lee, et al.**  
**Express Mail No.: EB 136719595 US**  
**Our Reference No.: 124269/A165US/00075**  
**Application No.: 10/526,839**  
**Title: Pyrazolopyridines And Methods Of Making And Using The Same**

Dear Sir:

Enclosed for filing please find:

- 1) Transmittal Form (PTO/SB/21);
- 2) Fee Transmittal Form (PTO/SB/17);
- 3) Petition for Extension of Time Under 37 CFR 1.136(a), PTO/SB/22;
- 4) Reply to the Restriction Requirement;
- 5) Copy of Office Action; and
- 6) Certificate of Filing by Express Mail.

We are also enclosing a post card receipt which we ask that you return to us acknowledging the date of receipt.

Very truly yours,

MILLER, CANFIELD, PADDOCK AND STONE,  
P.L.C.

By: 

Jonathan P. O'Brien Ph.D. / Reg. No.: 50,852

JPO/sjs

Enclosures

cc: Biogen Idec MA Inc. w/enclosures  
KZLIB:555484.1\124269-00075



UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/526,839 ✓

11/01/2005 ✓

Wen-Cherng Lee ✓

124269/00008/0075 ✓

1086

7590 07/31/2007  
Miller Canfield Paddock and Stone  
Jonathan P.O'Brien  
444 West Michigan Avenue  
Kalamazoo, MI 49007

RECEIVED

AUG 03 2007  
08/08/07  
BY MILLER CANFIELD, PLC  
Copy to Client 8/8/07

EXAMINER

THOMAS, TIMOTHY P

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

07/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/526,839 ✓

Applicant(s)

LEE ET AL. ✓

Examiner

Timothy P. Thomas

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**ENTERED****Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

**RECEIVED**

AUG 03 2007  
08/08/07  
BY MILLER-CANFIELD, PLC  
WXR

**Application Papers****Copy to Client 8/8/07**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 32-35, drawn to methods of inhibiting TGF $\beta$ .

Group II, claim(s) 36-37, drawn to methods of reducing the accumulation of excess extracellular matrix.

Group III, claim(s) 38-40, drawn to methods of treating a fibrotic condition.

Group IV, claim(s) 41-42, drawn to methods of inhibiting metastasis of tumor cells.

Group V, claim(s) 43-45, drawn to methods of treating a disease or disorder mediated by an overexpression of TGF $\beta$ .

**Note: Claims 1-31, compound claims, will be examined along with the elected Group.**

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature common to the groups is a compound of Formula I. Hashimoto et al. (JP 05-017470; 1993) have disclosed compounds (33 and 34) that anticipate the formula I structure. Furthermore, the compounds claimed in Formula I do not consist of a proper Markush group; there are multiple possible backbone structures. Therefore, the common technical feature is not a special technical feature. The methods claims (Groups II-VII) have different conditions, methods of implementation and/or outcomes of the method.

Art Unit: 1614

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- i) For any group elected, a single disclosed compound specie must be elected (e.g., claim 29); and
- ii) if either Group III or V is elected, a single disclosed condition, disease or disorder must be elected (e.g., claims 40, 45).

Note: if Group V is elected and one of the cancer species of claim 45 is also elected for (ii), the corresponding Group IV claims will be rejoined and examined together with Group V.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Art Unit: 1614

- i) all claims;
- ii) if Group III is elected: claims 38-40;
- ii) if Group V is elected: claims 43-45.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the compounds are distinct with different chemical and physical properties; some of the claimed compounds even have different core structures from others. As described above, Hashimoto teaches compounds of formula I, therefore the technical feature does not comprise a corresponding technical feature. The compounds are not proper Markush groups; they have different core structures; most of the compounds claimed have different core structures. The disclosed conditions, diseases and disorders are distinct; they have different etiologies, methods of treatment and characteristics.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.



Art Unit: 1614

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/526,839

Page 6

Art Unit: 1614

/TPT/

Timothy P. Thomas

Patent Examiner

*Phyllis Spivack*

PHYLLIS SPIVACK  
PRIMARY EXAMINER

**Notice of References Cited**



Application/Control No.

10/526,839

Applicant(s)/Patent Under

Reexamination

LEE ET AL.

Examiner

Timothy P. Thomas

Art Unit

1614

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	JP 05-017470	01-1993	Japan	Hashimoto, Kinji, et al.	C07D401/04
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	STN abstract of JP 05-017470 in English with structures; CAPLUS Accession # 1993:472619; Accessed 7/9/2007.
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



**CERTIFICATE OF FILING BY EXPRESS MAIL UNDER 37 CFR 1.10**

This is to certify that the following documents were mailed by U.S. Postal Service Express Mail, Reference No. EB 136719595 US to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 1, 2007.

- 1) Transmittal Form (PTO/SB/21);
- 2) Fee Transmittal Form (PTO/SB/17);
- 3) Petition for Extension of Time Under 37 CFR 1.136(a), PTO/SB/22;
- 4) Reply to the Restriction Requirement;
- 5) Copy of Office Action; and
- 6) Certificate of Filing by Express Mail.

MILLER, CANFIELD, PADDOCK AND STONE, P.L.C.

By: Sandy Sinotte